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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,782	12/27/2001	Lisa M. Parker	580755.003	9050

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STINSON MORRISON HECKER LLP  
ATTN: PATENT GROUP  
1201 WALNUT STREET, SUITE 2800  
KANSAS CITY, MO 64106-2150

EXAMINER

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/034,782

Applicant(s)

PARKER ET AL.

Examiner

Teena K Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: flanges 28 and height h. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the mask and an air source must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: Page 3, line 14, "...material the produces..." should be amended to read --material that produces--.

Correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "...said disk..." in line 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moulton (746,869).

Moulton in a mouthpiece discloses a flexible disk (1) configured to fit between a user's teeth and lips and seal the user's mouth (Fig. 1; Col. 1, lines 38-44).

With respect to the thickness of the disk, Moulton does not disclose expressly the thickness of the disk being less than or substantially equal to 1.5 mm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the disk thickness less than or substantially equal to 1.5 mm because based on the thickness of the disk a person using the disk can experience less jaw fatigue, as a thinner or thicker disk can maintain the natural contours of the facial structure of a user thereby, not stressing the facial muscles and providing a more comfortable fit for a user. Also based on a specific thickness of the

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disk a better seal around the mouth passage can be provided to different anatomical oral passageways of various user's as one thickness may not be applicable for another user as the facial contours for individual user's varies.

Furthermore, applicant has not disclosed that having a disk thickness less than or substantially equal to 1.5 mm provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious an obvious matter of design choice to modify Moulton to obtain the invention as specified in claim 1.

Claims 2 and 3 are equivalent in scope to claim 1 discussed above and is included in Moulton.

With respect to claim 4, Moulton discloses wherein said disk (1) is comprised of a material that naturally adheres to the interior of the user's lips and cheeks (Col. 2, lines 64-71).

With respect to claim 5, Moulton discloses the claimed invention except for the disk comprised of silicone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the disk of silicone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of choice, absent persuasive evidence that using a silicone has an advantage, is used for a particular purpose, or solves a stated problem. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

With respect to claim 10 Moulton discloses a one-way valve in said disk (2) configured to allow air to pass through said disk from an exterior of said disk to an interior of said disk.

Claims 12-16 are equivalent in scope to claims 1, 4, 5, and 10 discussed above and are included in Moulton.

**Claims 6-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moulton as applied to claims 1, 2, 4, and 10 above, and further in view of Balchly et.al. (4,270,531).**

The difference between Moulton and claim 6 is a bite block.

Blachly in a mouthpiece teaches a bite block assembly (12) providing a tight oral seal even in absence of teeth, and closed pulmonary ventilation of the patient is assured without the danger of atmospheric leakage or occlusion of the airway tube (Col. 2, lines 67 and 68 and Col. 3, lines 1-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mouthpiece of Moulton to employ any well known bite block doing so would have provided a tight oral seal even in the absence of teeth and closed pulmonary ventilation of a patient is assured without the danger of atmospheric leakage or occlusion of the airway tube including the bite block taught by Blachly.

With respect to claim 7, Blachly teaches an arm (20) and a flange (10) extending substantially perpendicular to said arm.

Claims 8, 9, and 11 are equivalent in scope to claims 1 and 7 discussed above and are included in Moulton/Blachly.

***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein (6,012,455).**

Goldstein in a mouthpiece discloses applying a mask (12) to cover a user's nose, wherein said mask is affixed to an air source (22) and inserting a mouthpiece (24) into the user's mouth, wherein said mouthpiece is configured to prevent air from leaking out of the user's mouth.

With respect to claim 18, Goldstein discloses wherein said mouthpiece adheres to the interior of the user's lips (Fig. 1).

With respect to claim 19, Goldstein discloses wherein said mouthpiece (24) comprises a bite block (26) affixed to an interior surface of said mouthpiece wherein said bite block is configured to position the user's lower jaw in a position that maintains an open airway.

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which**

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (6,012,455) in view of Moulton (746,869).**

The difference between Goldstein and claim 21 is a one-way valve in the mouthpiece.

Moulton in a mouthpiece teaches a one-way valve (2) providing a means for preventing the ingress of air through the mouth when breathing and to regulate its egress, so as to cause the air to be admitted to the lungs and expelled therefrom in the natural manner through nasal passages (Col. 1, lines 30-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mouthpiece of Goldstein to employ any well known valve doing so would have provided a means for preventing the ingress of air through the mouth when breathing and to regulate its egress, so as to cause the air to be admitted to the lungs and expelled therefrom in the natural manner through nasal passages including the one-way valve taught by Moulton.

Claim 22 is equivalent in scope to claim 21 discussed above and is included in Goldstein/Moulton.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show mouthpiece devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena K Mitchell whose telephone number is (703) 308-



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4016. The examiner can normally be reached on Monday-Thursday 5:30 AM to 4:30 PM.

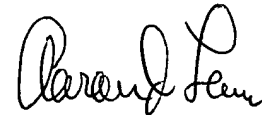
If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Primary Examiner Aaron Lewis can be reached on (703) 308-0716.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TKM  
TKM

October 1, 2002



Aaron J. Lewis  
Primary Examiner